

REMARKS

These remarks are being filed in response to the Official Action mailed in this application on September 11, 2007. A Request for Extension of Time (three months) accompanies these remarks. Claims 1 and 9-16 are pending in this application. Reconsideration of this application is respectfully requested in view of the following remarks.

Claims 1 and 15 were rejected under 35 U.S.C. §112, first paragraph, allegedly as failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

According to the action, “[T]he claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Specifically, the limitation --until after-- (as in “allowing the wound dressing to adhere to the wound and be left in place for a period of time *until after* epithelial outgrowth and vertical wicking into the dressing occur” (emphasis added)) is said to be outside the scope of the instant application. Applicants disagree.

Support for this concept is found throughout the specification. See, for example, pages 3 and 5. Additionally, see Example 2, where the dressing could be easily removed once re-epithelialization was complete. Then, cryosections of the dressing showed that the dressing fibers had swelled suggesting the dressing had vertically wicked the wound exudate away from the wound.

Applicants submit that there is ample support in the specification for the amendments made and request that this rejection be withdrawn.

Next, claims 1 and 9-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 3,842,996 (hereafter “Carlisle”) in view of U.S. Patent No. 5,899,893 (hereafter “Dyer, et al.”) and further in view of U.S. Patent No. 5,124,197 (hereafter “Bernardin, et al.”). Applicants respectfully traverse this rejection as well.

The present invention is concerned with a method of treating an acute wound using a wound dressing (as a substitute for a biological dressing or skin graft) wherein the wound dressing comprises highly absorbent fibers.

Applicants have found that by the use of absorbent fibers in the above method, fibrous dressings can be used as substitutes for biological dressings. Biological dressings are sophisticated and, therefore, tend to be expensive and carry the same risks of cross-contamination that are encountered with blood and blood products. The advantages of the new method embodied in Applicants' claims include that the dressings can be used as a substitute for a biological dressing at lower cost and without the risk of contamination.

Carlisle, on the other hand, is concerned with pressure dressings. According to Carlisle, pressure dressings are fundamental in the preparation of wounds for skin grafting (column 6, lines 36 to 37). Carlisle does not, therefore, consider his dressing as a substitute for a biological dressing, but rather as a preparation for it. Carlisle would not, therefore, motivate the person of ordinary skill in the art to use a fibrous dressing as a substitute for a biological dressing.

Further, dressings of Carlisle are dense, laminar dressings that wick laterally and bar the movement of exudate perpendicular to the plane of the dressing (column 3, lines 17-20). In use, the dressings of Carlisle are placed on the wound and, at dressing change time, the dressings are removed by delaminating or soaking or providing the dressings with a wound contact layer that has the property of release from the wound. Dressing changes occur every 12 hours or so. Carlisle does not, therefore, suggest that the dressings can be used in the manner of a biological dressing which is left in place in its entirety and undisturbed until the wound has healed. The differences between the method and dressing characteristics of Carlisle compared to Applicants' invention are shown particularly in the wording of Claim 13. Claim 13 has the method steps of: allowing the dressing to become adhered to the wound; leaving the dressing in place until it dries out to form a crust; and removing the dressing once the wound has healed. Carlisle does not disclose these steps and does not suggest them. Carlisle also does not teach that the dressing is left in place, or vertical wicking, both as required by Applicants' claims 1 and 9-12. In contrast, Carlisle discloses changing of the dressing, and only lateral wicking, and Carlisle does not suggest that there would be any advantage in vertical wicking.

Applicants' dressing and method are highly unusual in that, when used in the treatment of acute wounds as claimed, the dressing adheres to the wound. (See page 5, second paragraph). This type of behavior would usually only be seen with a biological dressing such as allograft, and it is a truly surprising discovery by the Applicants. It is illustrated particularly in Example 1, where it is described that the wound dressing dried out to form a crust as wound healing was in progress, and the dressing remained in place for 14 days. This method of use is very different from that contemplated in Carlisle where the emphasis is on the dressing being changed.

According to the action, the limitation "for a period of time until after epithelial outgrowth and vertical wicking into the dressing occur" fails to set forth any specific time or duration parameters. Applicants disagree. Certainly, depending on many factors, the amount of wound exudate and time to healing of a wound will vary. The claim language accounts for this variation.

The action then relies on Dyer, et al. to supply the deficiencies of Carlisle regarding the amount of water absorbed by the dressings. However, there is no suggestion in Carlisle to do so. While the Examiner argues at pages 6-7 of the action that there is ample motivation to combine Dyer, et al. and Carlisle to obtain a wound dressing that imparts vertical wicking, Applicants see no motivation for at least two reasons. First, Carlisle is concerned with pressure dressings. The dressings have a deep lamellar structure to give a highly dense dressing that is able to transmit pressure to the wound. For this reason, Carlisle selects its dressing materials carefully and specifically recites in claim 1 that the dressing should have limited compressibility. The limited compressibility means that the tape used to adhere the dressing to the wound can increase pressure application to the wound (column 1, lines 59-65). The dressing material of Dyer, et al. is a foam. It is well known that foams are highly compressible. A person having ordinary skill in the art would not, therefore, substitute the foam of Dyer, et al. for the lamellar dressing of Carlisle in order to improve the Carlisle dressing as the combination would mean that the Carlisle dressing no longer functioned as a pressure dressing. Second, neither Dyer, et al. nor Carlisle disclose vertical wicking or that the property would have an advantage when used in a dressing on an acute wound.

It is also implied on page 6 in the action that the amount of water absorbed by the dressings in Applicants' claims is nothing more than a difference in concentration. This treats Applicants' claims as though they related to a composition with different optimum ranges from a known composition. Clearly, that is not the case.

Next, the action relies on Bernardin, et al. for teaching absorbent webs of fibers with vertical wicking. However, it is clear from Bernardin, et al. that the expression "vertical wicking" is being used in the same manner as it is used in Dyer, et al. "Vertical wicking" is being used in Bernardin, et al. as the wicking of a vertically held strip of a test material against gravity. In relation to the wound, this wicking would be lateral, not perpendicular to the plane of the dressing. See column 8, lines 1-22, of Bernardin, et al. Thus, Bernardin, et al. does not teach vertical wicking in the same sense as it is used in Applicants' claims to mean wicking in a direction perpendicular to the plane of the dressing. (Similarly, the wicking in Dyer, et al. is the wicking of a vertically held strip of a test material against gravity. See column 4, lines 9 to 11, column 7, lines 41 to 43 and column 24, line 63, through column 26, line 2 of Dyer, et al.). There is no disclosure of vertical wicking in Bernardin, et al. (or in Dyer, et al.), nor is there a disclosure that the property of vertical wicking could be of an advantage when used to treat acute wounds.

As additional comments, Applicants note that it was argued in a previous rejection that Applicants have not demonstrated any unexpected or superior results through the use of their wound dressing method steps over that of the prior art. Applicants disagree. Applicants' dressing and method are highly unusual in that, when used in the treatment of acute wounds, the dressing adheres to the wound and forms a crust. This type of behavior would usually only be seen with a biological dressing such as allograft, and it is a truly surprising discovery. It is illustrated in Example 1, where it is described that the wound dressing dried out to form a crust as wound healing was in progress, and the dressing remained in place for 14 days.

It was also argued in a previous rejection that although the dressing of Carlisle must be saturated or provided with a wound contact layer to be removed, this does not impart patentability to the claims. However, Applicants made mention of this difference in method because Carlisle obviously removes the dressing before healing is complete

unlike Applicants' method. Contrast Carlisle's saturating and wound contact layer and the method steps these imply with steps c) and d) of claim 13.

The inventors of the present invention discovered that it is possible to treat burns by the use of a fibrous dressing that is able to wick vertically and becomes adhered to the wound. This behavior is truly surprising. Neither Carlisle, nor Dyer, et al., nor Bernardin, et al. mention vertical wicking as used herein, or that vertical wicking could be an advantage in a dressing used to treat acute wounds. Neither Carlisle, nor Dyer, et al., nor Bernardin, et al. disclose the method of treating an acute wound with a dressing that vertically wicks or that is left in place as has been claimed by Applicants. No combination of the teachings of Carlisle, Dyer, et al., and Bernardin, et al. suggest the claimed methods. For these reasons, Applicants believe that the claims are patentable over the cited documents.

Accordingly, withdrawal of the rejections, favorable reconsideration of this application, and allowance of the pending claims, are all earnestly solicited.

Respectfully submitted,

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